UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI EASTERN DISTRICT

UNITED STATES OF AMERICA,)
Plaintiff,)
v.) No. 4:24-CR-00010-RLW-SPM
ASIM MUHAMMAD ALI, M.D., and MOHD AZFAR MALIK, M.D.,)
Defendants.)

UNITED STATES OF AMERICA'S OPPOSITION TO MOHD AZFAR MALIK, M.D.'S MOTION TO DISMISS

COMES NOW the United States of America, by and through its attorneys, Sayler A. Fleming, United States Attorney for the Eastern District of Missouri, and Amy E. Sestric, Assistant United States Attorney for said District, and, opposes Defendant Mohd Azfar Malik, M.D.'s (Malik) Motion to Dismiss (ECF No. 55). Malik seeks dismissal of every count in the Indictment because he disputes whether his conduct violated federal regulations, incorrectly asserting that the Indictment misinterprets those federal regulations. Contrary to Malik's assertions, the Indictment accurately describes the governing regulations, and as the evidence at trial will establish, Malik's conduct indisputably violated not only those regulations, but, more importantly, the United States Criminal Code. Because the Indictment more than adequately states the charged offenses, Malik's Motion to Dismiss must be denied.

INTRODUCTION

Malik, a psychiatrist, agreed to hire co-conspirator Asim Muhammad Ali, M.D. (Ali), an internist, even though both knew that Ali had neither a Drug Enforcement Administration (DEA) registration to dispense controlled substances nor eligibility to bill the federal health care program

Medicare. But Malik allowed Ali to do both of those things—that is, administer potent controlled substances (often by intravenous injection) in violation of the Controlled Substances Act (CSA), 21 U.S.C. § 801, et seq., and submit services for payment to Medicare. With Malik's agreement, Ali did this without supervision. In fact, the two agreed that Ali could use Malik's DEA registration and Medicare billing credentials even though Malik was, for the most part, not in the building where the services were conducted and often times not even in Missouri. To conceal this conduct from detection, Malik signed medical notes as if he was the performing provider. After the fact, Malik paid Ali for each of his "services" on the side through one or more of his many businesses.

In his Motion to Dismiss, Malik asks the Court to dismiss every count in the Indictment. (Mot. to Dismiss, ECF No. 55, at 1.) Repeatedly latching on to regulatory provisions that he oversimplifies and reads too broadly, Malik asks the Court to find that his conduct qualified for a variety of exceptions. As explained below, each of Malik's arguments is premised on a misreading of the law and the insertion of his own version of the facts, which the United States disputes and, in any event, are not properly before the Court while deciding a motion to dismiss. *United States v. Welker*, 75 F.4th 820, 821 & n.3 (8th Cir. 2023) (outside allegations are not considered in assessing the sufficiency of an indictment, warranting denial of defendant's request to take judicial notice of documents outside the indictment). Malik's Motion to Dismiss should be denied in its entirety.

PROCEDURAL HISTORY

On January 10, 2024, a federal grand jury indicted Malik and Ali in a 22-count Indictment. The Grand Jury charged Ali and Malik with: (1) one count of conspiracy to illegally distribute controlled substances and to maintain drug-involved premises in violation of 21 U.S.C. § 846;

(2) one count of conspiracy to commit health care fraud in violation of 18 U.S.C. § 1349; (3) twelve counts of illegal distribution of a controlled substance in violation of 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2; (4) seven counts of making false statements related to health care matters in violation of 18 U.S.C. § \$ 1035 and 2; and (5) one count of maintaining drug-involved premises in violation of 21 U.S.C. § 856(a)(2) and 18 U.S.C. § 2.

On February 28, 2024, Malik filed his Motion to Dismiss (ECF No. 55). Ali waived pretrial motions. (Notice of Intent and Response to Show Cause, ECF No. 62.)

FACTS¹

The Indictment alleges the following:

At all relevant times, Malik, a psychiatrist, had two DEA registrations. (Indictment, ECF No. 2, ¶¶ 1, 8.) A DEA registration is required by federal law for any person who dispenses controlled substances. (*Id.* ¶ 5). At no point relevant to this case did co-defendant Ali have a DEA

In addition, the instant Motion to Dismiss adds that "[t]he business" earned more than \$9.8 million and the fraud alleged in the Indictment "was not even 1/100th of one percent of their receipts." (Mot. to Dismiss, ECF No. 55, at 2.) These unsupported allegations appear to overlook that Malik and Ali are charged in a health care fraud conspiracy and that Counts 15 to 21 of the Indictment charge mere exemplary crimes that are part of that conspiracy.

In any event, for purposes of deciding a motion to dismiss, all of Malik's statements about matters not in the Indictment must be disregarded. *Welker*, 75 F.4th at 821; *United States v. Farm & Home Sav. Ass'n*, 932 F.2d 1256, 1259 n.3 (8th Cir. 1991) ("In reviewing the sufficiency of an indictment, we accept the government's allegations as true, without reference to allegations outside the indicting document."); *United States v. Long*, No. 4:20-CR-486-RLW-SPM, 2023 WL 2571560, at *1 (E.D. Mo. Mar. 20, 2023) (same).

¹ The instant Motion to Dismiss in large part adopts the facts and procedural history set forth in Malik's Motion to Dismiss the Drug Trafficking Counts (the Drug Trafficking Motion) (ECF No. 54). The Drug Trafficking Motion contains a section entitled "Statement of Relevant Facts." (Drug Trafficking Mot., ECF No. 54, at 3.) That section sets forth a variety of facts not alleged in the Indictment, including irrelevant statements about Malik's purported educational and career-related accomplishments, as well as a statement that "all of the ketamine and Spravato treatments prescribed by Dr. Malik were necessary to treat patients with treatment-resistant depression." (*Id.* at 3-4.)

registration, which meant that he could not lawfully "administer" a controlled substance unless he was physically in the registered location and being directly supervised by and in the physical presence of the person under whose registration the controlled substance was being dispensed. (*Id.* ¶¶ 12-17).

In or about late 2018, Malik created the COPE Ketamine Clinic (COPE), a clinic designed to provide ketamine infusions. (*Id.* ¶ 39.) At no time did Malik have a DEA registration to administer controlled substances out of COPE, which was located in Suite 220 of the building located at 5000 Cedar Plaza Parkway in St. Louis, Missouri (the Cedar Plaza Building). (*Id.* ¶ 40.)

Beginning in or about December 2020, Malik and Ali agreed that Ali, who knew he could not administer controlled substances given his lack of a DEA registration, would use Malik's DEA registration to administer ketamine infusions to patients in Suite 220 of the Cedar Plaza Building without direct supervision by Malik and outside of Malik's presence. (*Id.* ¶ 41.) Malik knew that Ali did not have a DEA registration, and therefore, could not lawfully dispense controlled substances, including ketamine, without Malik's physical presence and supervision. (*Id.*)

Malik and Ali eventually agreed that Ali would also administer, while unsupervised, treatments of Spravato, a nasal spray containing the active ingredient controlled substance esketamine. (*Id.* ¶¶ 18, 46.) Due to the risks of sedation, dissociation, respiratory depression, and abuse and misuse, Spravato is only available through a restricted, Food and Drug Administration-mandated program called the Spravato Risk Evaluation and Mitigation Strategy Program (the REMS Program). (*Id.* ¶ 19.) Outpatient providers like Malik must be certified in the REMS Program in order to dispense Spravato. (*Id.*) To become enrolled in the REMS Program, outpatient providers, either directly or through their authorized representatives, must certify compliance with the REMS Program requirements. (*Id.* ¶ 20.)

Malik and Ali further agreed to illegally maintain drug-involved premises, in that they managed and controlled Suite 220 of the Cedar Plaza Building, and knowingly and intentionally made it available for the purpose of unlawfully storing and distributing ketamine and esketamine, as set forth above. (Id. ¶ 47.)

At all relevant times, Malik was an enrolled Medicare provider. (*Id.* ¶ 28.) Although Ali was for some time a Medicare and Medicaid provider (*id.* ¶ 29), in or about March 2020, he became suspended from participating in the Missouri Medicaid program. (*Id.* ¶ 30.) As a result, Ali had a duty to report this suspension to the Medicare program but did not do so. (*Id.* ¶¶ 30, 32.) Beginning in or about December 2020, Malik and Ali agreed that Ali would perform certain services for Medicare beneficiaries who were patients of Malik's psychiatric clinic, Psych Care Consultants, L.L.C. (PCC). (*Id.* ¶¶ 37, 49, 52.) Malik and Ali agreed that, in conducting these services, Ali would falsely use Malik's name and Medicare billing number, even though both Malik and Ali knew that Ali was not enrolled to provide Medicare services at PCC and that the services he provided were not reimbursable by Medicare. (*Id.* ¶ 52.)

Taking advantage of Malik's Medicare enrollment status, Malik and Ali caused Medicare to be fraudulently billed for Annual Wellness Visits and services related to Spravato treatments that were conducted by Ali but billed as if they had been conducted by Malik. (*Id.* ¶¶ 53-54.) When Ali provided Annual Wellness Visits and Spravato services associated with treatments, he and Malik further agreed to conceal that Ali was the actual rendering provider by having Malik, not Ali, sign medical notes associated with the services. (*Id.* ¶ 55.)

STANDARD

Federal Rule of Criminal Procedure 12(b)(3)(B)(v) provides that a motion to dismiss may be filed for failure to state a claim. To assess such a motion, the Court must accept the allegations

Stated in the Indictment as true and "ask whether they can form the basis of the charged offense." United States v. Hansmeier, 988 F.3d 428, 436 (8th Cir. 2021). "An indictment adequately states an offense if: it contains all of the essential elements of the offense charged, fairly informs the defendant of the charges against which he must defend, and alleges sufficient information to allow a defendant to plead a conviction or acquittal as a bar to subsequent prosecution." United States v. Hayes, 574 F.3d 460, 472 (8th Cir. 2009) (quoting United States v. Sewell, 513 F.3d 820, 821 (8th Cir. 2008)). Further, "[a]n indictment is normally sufficient if its language tracks the statutory language. Sewell, 513 F.3d at 821. In assessing the sufficiency of an indictment, courts accept the Government's allegations as true, "without reference to allegations outside the indicting document." Farm & Home Sav. Ass'n, 932 F.2d at 1259 n.3; Welker, 75 F.4th at 821; Long, 2023 WL 2571560, at *1.

When deciding a motion to dismiss an indictment pursuant to Rule 12(b), courts "are not to make factual findings on issues that relate to the jury's decision on the merits, but rather, must defer such matters for trial." *United States v. Haning*, No. 4:18-CR-139-RWS-NAB, 2019 WL 9834329, at *17 (E.D.Mo. Aug. 20, 2019) (denying defendant's motion to dismiss the indictment, finding that defendant could make "the argument in the context of a Rule 29 motion once the Government has introduced evidence at trial"). A court "simply cannot approve dismissal of an indictment on the basis of predictions as to what the trial evidence will be." *United States v. Ferro*, 252 F.3d 964, 967–68 (8th Cir. 2001) (quoting *United States v. DeLaurentis*, 230 F.3d 659, 661 (3d Cir. 2000)). "To warrant dismissal, it must be clear from the parties' agreed representations about the facts surrounding the commission of the alleged offense that a trial of the general issue would serve no purpose." *United States v. Pope*, 613 F.3d 1255, 1261 (10th Cir. 2010). Citing the Supreme Court's decision in *United States v. Covington*, 395 U.S. 57, 60 (1969),

the First Circuit has held that "a court must deny a motion to dismiss if the motion relies on disputed facts." *United States v. Stepanets*, <u>879 F.3d 367, 372</u> (1st Cir. 2018).

<u>ARGUMENT</u>

Malik contends that the Indictment should be dismissed because, according to him, he complied with certain regulations that exonerate him from criminal liability. However, as discussed below, each of Malik's arguments is premised on a combination of unsubstantiated factual assertions that fall outside the Indictment and incorrect readings of the cited regulations. Malik's Motion to Dismiss should be denied.

A. The Indictment Properly Alleges that Malik Maintained Drug-Involved Premises in Violation of the CSA.

Malik seeks dismissal of Count 1 (conspiracy to illegally distribute controlled substances and to maintain drug-involved premises) and Count 22 (maintaining drug-involved premises). As justification for this request, Malik states he was registered to dispense drugs from a *different* suite in the Cedar Plaza Building than the one from which Ali, with no DEA registration and no supervision, conducted ketamine infusions and Spravato treatments. In essence, Malik contends that, as long as he was DEA-registered anywhere in the Cedar Plaza Building, he and Ali were authorized to dispense and store medications from any office within that building. As authority, Malik cites 21 C.F.R. § 1301.12(a)—the CSA regulation requiring separate DEA registrations for separate sites.

Malik's focus on 21 C.F.R. § 1301.12(a) mischaracterizes both the Indictment and the language of the regulation. As set forth below, Counts 1 and 22 allege violations of 21 U.S.C. § 856 because Malik managed and controlled premises (namely, Suite 220 of the Cedar Plaza Building) for the purpose of illegally storing and distributing ketamine and Spravato. The Indictment does not, as Malik insinuates, merely allege that he failed to comply with 21 C.F.R.

§ 1301.12(a) alone. In any event, Malik *did* violate 21 C.F.R. § 1301.12, which clearly required him to separately register Suite 220 of the Cedar Plaza Building prior to storing and dispensing controlled substances there.

1. Malik Violated § 856 of the CSA Because He Managed COPE for the Purpose of Illegally Distributing Ketamine and Spravato.

Malik's argument to dismiss Counts 1 and 22 is based solely on 21 C.F.R. § 1301.12(a). However, Counts 1 and 22 invoke two theories of liability, one of which is totally independent of 21 C.F.R. § 1301.12(a).

Certainly, the failure to register Suite 220 at all is one reason why it was illegal for Malik and Ali to distribute ketamine from it. But that is not the only reason: it was illegal for Malik to manage and control Suite 220 for the purpose of having Ali—who had no DEA registration—administer controlled substances outside of Malik's presence and without his supervision. For reasons discussed in the United States' Opposition to Malik's Drug Trafficking Motion (ECF No. 64-1), these acts were plainly illegal under the CSA.

Thus, Malik misses the point when he states that, under the Government's theory, "had [he] brought his patients one floor up for their treatments, he would have been a law-abiding citizen, but because he had them receive their treatments one floor down, he was a drug trafficker." (Mot. to Dismiss, ECF No. 55, at 4.) Not so. Malik did not merely bring his patients down one floor; he had them receive their controlled substance administrations from an unsupervised coconspirator who had no DEA registration while Malik was not even in the building. (Indictment, ECF No. 2, ¶¶ 41-46.) These acts were illegal regardless of where they occurred or whether the site was DEA-registered pursuant to 21 C.F.R. § 1301.12(a).

Because Malik managed and controlled Suite 220 for the purpose of effectuating illegal distribution of ketamine and Spravato, he maintained drug-involved premises in violation of 21 U.S.C. § 856(a)(2), irrespective of any compliance with 21 C.F.R. § 1301.12(a).

2. Malik Violated the Unambiguous Terms of 21 C.F.R. § 1301.12—and the CSA.

In any event, Malik did not comply with 21 C.F.R. § 1301.12(a), which is entitled "Separate registrations for separate locations" and reads:

A separate registration is required for *each* principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

(emphasis added). Malik argues he unquestionably complied with this provision because, he says, he was registered to dispense from Suite 350 of the Cedar Plaza Building,² which was only one floor above the COPE ketamine clinic located in Suite 220. Malik explains that "Suites 350 and 220 were, together, [his] 'principal place of professional practice at one *general physical location*' for purposes of the DEA registration requirement" (Mot. to Dismiss, ECF No. 55, at 4 (emphasis in original).)

Malik both misquotes and misinterprets the regulation, which in fact provides that a registration is required for "each principal place of business or professional practice at one general physical location" where controlled substances are dispensed. 21 C.F.R. § 1301.12(a) (emphasis added). Malik's interpretation—under which any registration in a given physical location suffices—reads the word "each" out of the regulation. The word "each," which is also present in

² Citing paragraphs 8 through 10 of the Indictment, Malik states "it is undisputed that [he] was registered to, and therefore lawfully could, dispense controlled substances directly to patients from Cedar Plaza Suite 350" (Mot. to Dismiss, ECF No. 55, at 4.) However, that is not what paragraphs 8 through 10 of the Indictment say. Rather, at most, they indicate that, after February 2023 (long after the alleged conduct began), Malik was DEA-registered at Suite 350 of the Cedar Plaza Building. (Indictment, ECF No. 2, ¶¶ 8-10, 34.)

the regulation's corresponding CSA statutory component,³ means that one location (such as Suite 350) does not suffice if another "professional practice" at the same "general physical location" is also dispensing controlled substances.

To adopt Malik's interpretation of the separate registration requirement would create an absurd result. Take, for example, a large medical building on a hospital campus. Under Malik's view, as long as a practitioner is DEA-registered to dispense controlled substances in one suite of the building (i.e. the "general physical location," according to Malik), every other suite in the same medical building would also be so authorized.

Such an interpretation would undermine the very purpose of the provisions of the CSA. In enacting the CSA, "Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels," and "[i]t was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *United States v. Moore*, 423 U.S. 122, 135 (1975). If, as Malik would have it, the registration of a single suite in a large medical building justified the non-registered dispensing of controlled substances from every other suite in the same building, the CSA's provisions would be difficult, if not impossible, to enforce, and the requirement to procure a registration would be nearly meaningless. Merely by way of example, the CSA provisions authorizing DEA administrative inspections and warrants⁴ would be extremely challenging to implement, at best, and unenforceable, at worst. If, say, the DEA attempted to execute an administrative inspection, Malik would expect investigators to show up to the registered

³ 21 U.S.C. § 822(e)(1) ("A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.").

⁴ See, e.g., <u>21 U.S.C. §§ 822(f)</u> & <u>880</u>; <u>21 C.F.R. § 1316.03</u>.

suite and then go knocking on door-to-door searching for additional suites in a given medical building where controlled substances could be stored and dispensed.

More rational is the interpretation that gives meaning to every word in 21 C.F.R § 1301.12(a), including the word "each." The regulation plainly requires a separate registration for "each," not "any," "professional practice at one general physical location" where controlled substances are dispensed. In fact, the language expressly contemplates situations like the instant one, where a general physical location, such as the Cedar Plaza Building, has more than one "professional practice" where controlled substances were dispensed, such as PCC and COPE. The regulation makes clear that "each" of those practices needs their own registration if they intend to dispense controlled substances.⁵

Malik's interpretation of the separate registration requirement is further undermined by another subsection of 21 C.F.R. § 1301.12. Specifically, part (b) of that regulation lists locations that are deemed "not to be places where controlled substances are manufactured, distributed, or dispensed," and thus do not require a separate registration. One of the exempted locations is:

[a]n office used by a practitioner (who is registered at another location in the same State in which he or she practices) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

21 C.F.R. § 1301.12(b)(3) (emphasis added). Because an "office" is exempted only if controlled substances are *not* administered or stored there, certainly, then, an "office" (such as Suite 220)

⁵ Malik's reference to a DEA website authorizing parking lot administrations of controlled substances during the COVID-19 pandemic only underscores the level of specificity required by the DEA when registering a location. Even in a public health emergency, the authorization allows administration of controlled substances in the parking lots of DEA-registered facilities only "so long as a provider's parking lot is located *immediately adjacent* to the provider's DEA-registered facility." Available at https://deadiversion.usdoj.gov/faq/coronavirus-faq.html (emphasis added).

where controlled substances *are* stored and administered on a regular basis (as they were at COPE) is an unexempted category that requires separate registration.

Contrary to Malik's arguments, none of this is unconstitutionally vague. The defendants in *United States v. Clinical Leasing Service, Inc.* made a similar argument that the Fifth Circuit rejected. 925 F.2d 120 (1991). The defendants argued that the phrase "each principal place of business" was unconstitutionally vague because it suggested that practitioners need only register at their primary place of business and not necessarily every place of business. *Id.* at 122. Disagreeing, the court found it was sufficiently clear that the provisions applied not to a single principal place of business, and that "[a] physician of ordinary means and intelligence would understand that the federal registration provisions apply to *each* important or consequential place of business where the physician distributes controlled substances." *Id.* at 123 (emphasis in original). The court rejected the defendants' notion that they were only required to register "a single important or consequential place of business where controlled substances are distributed." *Id.* (emphasis in original). The court also noted that the defendants had "little right to argue . . . that they were misled by the 'ambiguous' language of the federal registration provisions," because they previously had been warned their conduct was noncompliant and yet carried on. *Id.*

At trial, the United States will present evidence that Malik was warned that Suite 220 needed a separate DEA registration, and yet carried on operating a ketamine clinic out of it without obtaining one. Because 21 U.S.C. § 822(e) and 21 C.F.R. § 1301.12(a) unambiguously required a separate registration for Suite 220, Malik's request to dismiss Counts 1 and 22 should be denied.

B. Counts 1, 5, and 6, Which Charge Malik with Illegally Distributing Spravato in Violation of the CSA, Are Not Premised on Mere Noncompliance with the REMS Program.

Malik contends that Counts 1, 5, and 6, which charge him with illegally distributing the controlled substance Spravato, must be dismissed for two reasons. First, he says that he complied with all the REMS Program requirements. Second, he alleges that the REMS Program requirements cannot serve as the basis for criminal liability.

The Court does not need to decide whether Malik complied with the REMS Program requirements, which, in any event, raises disputes beyond the Indictment not proper for a motion to dismiss. *Welker*, 75 F.4th at 821. Spravato is a controlled substance. (Indictment, ECF No. 2, ¶ 18.) Thus, it was illegal for Malik to allow Ali to administer it outside of his presence and without supervision for all the same reasons that it was illegal for Malik to allow Ali to conduct ketamine infusions in the same fashion. (*See* United States' Opp. to Malik's Drug Trafficking Motion, ECF No. 64-1, at 7-18.) When it comes to the Spravato distribution counts, Malik hones in only on the REMS Program requirements. But the Indictment clearly alleges that Ali's distribution of Spravato was illegal because it was "outside of Dr. Malik's presence and without supervision, even though . . . Malik knew he was required [not only to] satisfy the REMS Program requirements, [but also] to provide direction supervision, and to be physically present for Spravato treatments " (Indictment, ECF No. 2, ¶ 45.)

Thus, Malik is culpable for Counts 1, 5, and 6 regardless of his compliance with the REMS Program requirements. That said, the REMS Program is still relevant to Malik's criminal state of mind. At trial, the United States will present evidence that Malik knew about the REMS Program requirements, that he knew about Spravato's risks of sedation, dissociation, respiratory depression, abuse and misuse, and that he nonetheless allowed Ali to administer Spravato using his DEA

registration without supervision and outside of his presence. In short, the REMS Program requirements, although relevant to Malik's criminal intent, do not serve as the legal basis for Counts 1, 5, and 6, and Malik's motion to dismiss them should be denied.

C. By Falsely Representing that Malik Performed Services Actually Conducted by Ali, Malik and Ali Made Misrepresentations to the Medicare Program that Were "Material," An Issue in the Exclusive Province of the Jury.

In another attempt to improperly raise matters outside of the Indictment, Malik seeks dismissal of the counts related to health care fraud, Count 2 and Counts 15 through 21. He asserts that the facts alleged in the Indictment are wrong because, he says, Ali's services were in fact reimbursable by Medicare because Ali was a licensed provider directly supervised by Malik. (Mot. to Dismiss, ECF No. 55, at 9.) This argument, which is based on misconstrued descriptions of Medicare rules and regulations, is a factual dispute that cannot provide the basis for dismissal of an indictment. *Covington*, 395 U.S. at 60.

1. Medicare Would Not Have Paid for the Annual Wellness Visits Had It Known the Claims Were Billed Under Malik's Name Even Though Ali Performed the Services.

Citing 42 C.F.R. § 410.15(b), Malik contends that he could bill for Annual Wellness Visits performed by Ali. Specifically, he alleges that the regulation allows any "licensed practitioner" to perform Annual Wellness Visits "under the direct supervision" of a physician, and that "direct supervision" was expanded during the relevant timeframe to include virtual assistance by the supervising provider (i.e. Malik) if immediately available to the "licensed practitioner" (i.e. Ali). (Mot. to Dismiss, ECF No. 55, at 10-11.) Malik's argument is flawed for several reasons.

First, it asks the Court to make a factual finding that Malik was immediately available to provide virtual assistance to Ali whenever necessary. This unsubstantiated assertion falls outside the Indictment, and thus cannot be considered in deciding a motion to dismiss. *Welker*, 75 F.4th

at 821; Farm & Home Sav. Ass'n, 932 F.2d at 1259 n.3; Long, 2023 WL 2571560, at *1. Moreover, Malik's position that Medicare would willingly pay for Ali's services essentially amounts to an argument that the misrepresentations made to Medicare were not material to its decision to pay for the Annual Wellness Visits; this is a question for the jury. Ferro, 252 F.3d at 967 (reversing dismissal of indictment based on the Supreme Court's holding that, "when materiality is an element of a criminal fraud offense, the question of materiality must be submitted to the jury" (citing United States Gaudin, 515 U.S. 506, 523 (1995)). The Court should deny Malik's request to dismiss Count 2 and Counts 15 through 19 for these reasons alone.

But even if these matters were properly before the Court now, they still would not warrant dismissal. Regardless of the enrollment status of the rendering provider, Medicare will not reimburse for services that deliberately misrepresent or conceal the identity of the rendering provider, which is precisely what the Indictment alleges Malik and Ali did. (Indictment, ECF No. 2, at ¶¶ 28, 52).

Additionally, even if Malik's argument did not rest on a disputed question of fact regarding Malik's supervision, and even if Medicare would reimburse claims that deliberately misrepresent the rendering provider, Malik's argument *still* fails, because Ali was not a legitimately enrolled Medicare provider. As the Indictment alleges, although Ali was enrolled as a Medicare provider beginning at latest in December 2003, he was *never* enrolled as provider at PCC, the practice at which he rendered services billed under Malik's name. (Indictment, ECF No. 2, ¶ 29.) Further, as a Medicare provider, Ali had certain obligations, including to inform Medicare if he was suspended from the Medicaid program and if he had an update in his practice location. (*Id.* ¶¶ 31-32; *see also* 42 C.F.R. § 424.516(d) (requiring physicians to report changes or additions in practice locations, as well as "[a]ll other changes in enrollment," in order to maintain enrollment in

Medicare.⁶) Yet, Ali did not notify Medicare when he was suspended from Medicaid in March 2020 or when he became affiliated with Malik in December 2020. (Indictment, ECF No. 2, ¶¶ 30-32.) As a result, Ali was not enrolled or otherwise permitted to provide Medicare services at PCC. (*Id.* ¶ 32.) In fact, if Medicare had known of his omissions, it would have revoked him from participation. (*Id.* ¶ 32; *see also* 42 C.F.R. § 535(a)(9) (revocation for failure to meet reporting requirements) & (12) (revocation for termination, revocation, or other form of bar from participation in a state Medicaid program).⁷) In short, Ali could not bill Medicare for services. Malik's request to dismiss Count 2 and Counts 15 through 19 should be denied.

2. The Indictment Does Not Allege (and the Evidence Will Not Support) that the Services Ali Provided to T.A. Were "Incident To" Malik's Services.

Malik's arguments to dismiss Counts 20 and 21 fail for reasons similar to his arguments to dismiss the Annual Wellness Visit counts, above. Counts 20 and 21 allege that Malik and Ali fraudulently represented to Medicare that Malik had performed services for T.A. that were in fact performed by Ali. (Indictment, ECF No. 2, ¶ 61.) Malik contends these counts fail to state a claim because, he says, they were properly billed as "incident to" Malik's services pursuant to 42 C.F.R. § 410.26(b), which provides that "Medicare Part B pays for services and supplies incident to the

⁶ Citing the Medicare Program Integrity Manual, Malik contends that Ali's Medicaid suspension was not an event subject to reporting requirements. (Mot. to Dismiss, ECF No. 55, at 14-15 & n.6.) This matter outside of the pleadings is not properly before the Court in connection with a motion to dismiss. *Welker*, 75 F.4th at 821. At trial, the Government will present evidence that Ali, as he knew, was required to disclose his March 2020 Medicaid suspension.

⁷ Malik concedes these provisions give CMS discretion to revoke a provider's Medicare enrollment, but argues that Ali had not, in fact, been revoked. Accordingly, Malik concludes that Ali was eligible to provide Medicare-reimbursed services. (Mot. to Dismiss, ECF No. 55, at 14-15.) This argument misses the point. The Indictment alleges that Ali violated a duty to disclose material information to Medicare, and that, had he fulfilled that duty, Medicare would have revoked his participation. (Indictment, ECF No. 2, ¶¶ 30-32.) The various misrepresentations and omissions that occurred were material to Medicare's decision to pay claims that deliberately misrepresented Malik as the rendering provider. Ferro, 252 F.3d at 967 (questions of materiality are within the province of the jury).

service of a physician (or other practitioner)." Lawful "incident to" billing, which is discussed in

42 C.F.R. § 410.26(b)(1)-(9), has numerous parameters and requirements, including that the

services be rendered in compliance with state law (which the Spravato treatments were not). Malik

and Ali's compliance with those many and detailed provisions necessarily requires this Court to

weigh facts and evidence, none of which may properly be done in the context of a motion to

dismiss. Neither Malik nor the Indictment address these requirements. Malik's motion to dismiss

Counts 20 and 21 should be denied.

CONCLUSION

WHEREFORE, the United States respectfully asks the Court to **DENY** Mohd Azfar Malik,

M.D.'s Motion to Dismiss (ECF No. 55) in its entirety.

Respectfully submitted,

SAYLER A. FLEMING

United States Attorney

/s/ Amy E. Sestric

AMY E. SESTRIC, #66219MO

Assistant United States Attorney

CERTIFICATE OF SERVICE

I hereby certify that on March 28, 2024, the foregoing was filed electronically with the

Clerk of the Court to be served by operation of the Court's electronic filing system upon all

Counsel of Record.

/s/ Amy E. Sestric

AMY E. SESTRIC, #66219MO

Assistant United States Attorney